1. Definitions
   a. **Bx.** – Biopsy
   b. **CCPM** – Center for Cancer Precision Medicine
      i. Research samples for CCPM collaboration projects are separate from the biopsy initiative described in this document. **Collaborating research groups must communicate with CCPM project managers to schedule sample collection events.**
   c. **CRC** – Clinical Research Coordinator, CRC and Study Coordinator are interchangeable terms
   d. **CSIR** – Cross-sectional Interventional Radiology
   e. **DCBC** – Dana-Farber CSIR Bx. Collections
      i. An initiative to collect research biopsy samples from CSIR for DFCI research protocols. **The service described here excludes all CCPM collaborations.** The collection events for DCBC are scheduled through CSIR REDCap and calendar invites sent to **DFCI_Bx_CollectionsOPS@dfci.harvard.edu** by research coordinator.
   f. **EOB** – End of Business Day
   g. **MRN** – Medical Record Number
   h. **OCT compound** - Optimal Cutting Temperature compound

2. Scheduling and DCBC Notification
   a. Patient is consented to study protocol per disease center.
   b. Epic CSIR biopsy is ordered by designated disease center personnel.
      i. Best practice – Add details of the research protocol to the EPIC order
         1. Protocol numbers
         2. Treatment vs. Non-Treatment
      ii. Optional information to include whenever possible:
         1. Requested number of cores per study
         2. Priority above or below pathology samples

"NOTE: THIS DOCUMENT IS FOR DFCI/CSIR BIOPSY COLLECTIONS ONLY. FOR INFORMATION REGARDING CCPM PROJECTS, PLEASE CONTACT KARLA HELVIE (karlae_helvie@dfci.harvard.edu)."
c. Once the biopsy is scheduled, the research coordinator sends a calendar invite to the DFCI Biopsy Collections Operations calendar (Dfci_Bx_CollectionsOps@DFCI.HARVARD.EDU) calendar using the sample template below (a blank template can be found in Appendix A):

**DFCI CSIR Bx. Collections invite**
Patient: Jane Doe DFCI MRN: 123456, BWH MRN: 87654321
Sample ID: COLFR999999
Biopsy date and time: 4/18/19 @ 11:00 AM

*Designated Primary CRC: Joe Smith, #11-222, 99-999*
Alternate CRC: Jennifer Williams, #33-444, Protocol 99-999
Primary CRC: James Brown, #55-666, Protocol 98-989
Alternate CRC: Jennifer Jones, #77-888, Protocol 98-989
Research group: GI
Procedure description: omentum biopsy

**Tissue priority:**

<table>
<thead>
<tr>
<th>Priority</th>
<th>Tissue Amount</th>
<th>Media</th>
<th>Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>1 core</td>
<td>Formalin</td>
<td>Pathology</td>
</tr>
<tr>
<td>#2</td>
<td>1 core</td>
<td>Formalin</td>
<td>99-999</td>
</tr>
<tr>
<td>#3</td>
<td>2 cores</td>
<td>DMEM</td>
<td>98-989</td>
</tr>
</tbody>
</table>

i. How to use template:
   1. Provide name and MRN for all patients so we may identify them in CSIR
      a. Sharing PHI with DCBC is permissible under core facility access
      b. Procedure information includes date and time as well as the type of procedure to be performed
      c. Contacts:
         i. Designated Primary CRC interfaces with techs and is first point of contact.
            1. Must communicate timing of the case and tissue pick-up with CRCs associated with any additional protocols
         ii. Alternate CRC name and pager to serve as backup if primary CRC is unavailable to answer questions or to facilitate tissue pick-up
         iii. Primary and Alternate contacts must be established for each protocol involved
   d. Priority list
      i. List the allocations with the total number of cores needed in each media type, along with the protocol associated with that sample
      ii. List should be ordered to indicate the importance of that allocation
      iii. Samples for pathology may not need to be the first priority and DCBC will communicate this to the radiologist. Please note that the attending radiologist retains the right to send samples for pathology review based on their clinical judgement
ii. Best practice – if 2+ research protocols are indicated, DCBC will connect all the coordinators to create a single priority list for allocations.  
   1. Ordering physicians and oncologists may need to be notified by the CRCs to confirm that the priority list is clinically optimized.

iii. DCBC calendar invites are separate from CCPM invites. If a case is scheduled through a CCPM protocol, only send invites via the established CCPM process. If a case has both a CCPM component and DCBC component, please send the calendar invite to the DCBC email and note the protocol number that is a CCPM collaborative study. An additional email to the PM of the CCPM study from the study coordinator will loop in the CCPM staff and CCPM staff will coordinate with DCBC.  
   1. See Appendix C for comparisons of DCBC and CCPM collaborative projects.

iv. If the biopsy is rescheduled, it is the CRC’s responsibility to update the calendar invite.  
   1. DCBC will amend CSIR REDCap forms as needed.  
   2. If biopsy is rescheduled to the same day or the next day, the CRC will update the calendar invite and contact DCBC by phone.  
      a. DCBC will contact CSIR and communicate the change.  
      b. DCBC will work with the coordinator to form a collection plan, but cannot guarantee that it can be accommodated.

v. DCBC will perform a check at 3:30 pm the day before the procedure for the following items:  
   1. CSIR REDCap form submitted for all protocols.  
   2. Calendar invite sent to DCBC inbox.  
   3. Trial materials are handed off to DCBC team.

vi. DCBC will work with the coordinator(s) to ensure that all cases have these completed, but we cannot guarantee accommodating cases that do not have all three completed by 5:00pm the day before the procedure.  
   1. If a case is scheduled for the same day or next day, or rescheduled for the same day or next day, please contact DCBC directly by phone and we will work with you to make a collection plan.  
      a. DCBC will inform CSIR of the same-day addition.  
      b. DCBC cannot guarantee that cases that are scheduled for the same day can be accommodated.

3. Pre-Procedure Responsibilities
   a. Research Coordinator
      i. Enter biopsy information into CSIR Research Specimen Additional Information Form (REDCap database) as soon as patient is scheduled for biopsy and consented for research.  
         1. DCBC will perform check of next-day research biopsies in CSIR and ensure the CSIR REDCap database is populated accordingly.  
            a. This check is performed at 3:30pm the day before the procedures.  
            b. DCBC will reach out to coordinators to submit missing REDCap forms.  
      2. https://redcap.partners.org/redcap/surveys/?s=M4DTNPNAFF  
         a. Forms for multiple protocols can be submitted separately or together.  
         b. Include relevant language for research biopsy:  
            i. Specify clinical or research purpose of biopsy and DFCI study xx-xxx, if known.  
            ii. Clinical Trial  
            iii. Tissue Banking
iv. Clinical Trial and Tissue Banking
   c. Specify "Please call CCPM (617-582-9353) at start of procedure for research specimen collection. Please contact xxx (CRC) for any questions (xxx-xxx-xxxx)".

ii. Drop off labeled kit to Path Team at least one day before scheduled procedure.
   1. Drop-off location is Dana 933 in blue box marked “CRC kit drop-off.”
   2. The kit must contain printed CSIR REDCap form that indicates the protocol number specific to that kit.
   3. Containers in kit must be labeled with patient name and MRN, as well as what media type (if applicable) and the fill and expiration dates.
   4. De-identified labels must be supplied in the kit along with instructions on how to label the samples.
   5. CRCs are ultimately responsible that samples are de-identified and labeled correctly before distributing to research facilities.

iii. Aliquoted containers of media should also be dropped off with DCBC team on Dana 933.
   1. Refrigeration is available, but please note that space is limited.
   2. Drop-off of tubes no more than 2 days before day of procedure.
   3. Tubes must be labeled with patient name, MRN, protocol number for the sample, and the date filled.
      a. If media is not used on the day of procedure, it will be discarded after the collection is completed.

b. DCBC Team Member - Pathology Technician
   i. Each staff member will review their assigned cases for priority list, special collection requests, clinical trials, CRC contact information.
   ii. DCBC number (617-582-9353) will be assigned to one individual to communicate with CSIR staff.
      1. This number rotates through all Path team personnel and is assigned on Monday of each week. If coverage is needed, the individual must coordinate with the team to ensure full coverage.
      2. Exceptions may be made for holidays and emergency days, pending approval from the Associate Director.

4. Day of Procedure Workflow
   i. CSIR will contact DCBC phone (617-582-9353) to notify team when patient is entering room.
   ii. DCBC tech will page designated primary research coordinator when patient is entering room to notify start of procedure. If the patient is consented for multiple protocols, this designated primary CRC must contact the other primary coordinators with updates.
      1. If the procedure is delayed by 90 minutes or more, DCBC tech will page designated primary CRC to update them on patient status.
      2. If the research coordinator contacted by CSIR instead of path tech, they will contact DCBC team at 617-582-9353.
      3. Research coordinator may also track procedure via Epic.
   iii. DCBC tech will go to CSIR immediately when called by CSIR staff or if Epic schedule indicates that the patient has entered the IR room.
   iv. Contact the designated research coordinator(s) via page for tissue pick-up at BWH Laboratory Control on Amory 2.
      1. The clock for the 30 minute window begins at the time of the initial page from the DCBC tech to the designated primary coordinator.
Timeline for tissue pick-up

- <10 Minutes after completing allocation – DCBC tech pages designated CRC
- 10 – 30 minutes after page is sent – CRC reaches out to DCBC tech via callback number and meets at Lab Control on Amory 2 for tissue pickup
  - *Designated CRC notifies other coordinators that tissue is available*
- 30 – 60 minutes after page is sent – CRC is responsible for arranging tissue pickup from DCBC tech
  - DCBC Tech confirms new pickup location based on schedule
  - We will follow up weekly with CRMs to review any cases that were not picked up within 30 minutes
- >60 minutes after page is sent – Notification for tissue pickup escalated in the following order:
  - Clinical Research Manager, Treating Physician, Principal Investigator(s), Clinical Research Leader, Disease Center Leader

*Designated research coordinator is responsible for contacting additional coordinators for if multiple protocols are indicated. DCBC will not be able to contact more than one coordinator for pick up.

v. Email collection summary to clinical research coordinators (respond to email invites)
   1. Collecting DCBC tech sends email within 24 hours of completion.
   2. Example email:

   **DFCI CSIR Bx. Collections invite**
   Patient: Jane Doe DFCI MRN: 123456, BWH MRN: 87654321
   Sample ID: COLFR999999
   Biopsy date and time: 4/18/19 @ 11:00 AM
   ***Designated Primary CRC: Joe Smith, #11-222, 99-999***
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   Primary CRC: James Brown, #55-666, Protocol 98-989
   Alternate CRC: Jennifer Jones, #77-888, Protocol 98-989
   Research group: GI
   Procedure description: omentum biopsy

   Hello Study Team,

   Please see the chart below for the allocations that were made for this case.

   **Tissue priority:**

<table>
<thead>
<tr>
<th>Priority</th>
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<th>Media</th>
<th>Protocols</th>
<th>DCBC</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>1 core</td>
<td>Formalin</td>
<td>Pathology</td>
<td>2 Cores (#1, #2)</td>
</tr>
<tr>
<td>#2</td>
<td>1 core</td>
<td>Formalin</td>
<td>99-999</td>
<td>1 Core (#3)</td>
</tr>
<tr>
<td>#3</td>
<td>2 cores</td>
<td>DMEM</td>
<td>98-989</td>
<td>3 Cores (#4, #5, #6)</td>
</tr>
</tbody>
</table>

   Collection notes: cores #4, 5, 6 were fragmented.

   Thank you.
Appendices

Appendix A: Email template

EXAMPLE:

DFCI CSIR Bx. Collections invite
Patient: Name including (DFCI MRN:, BWH MRN:)
Sample ID:
Biopsy date and time:
*Designated Primary CRC: Includes contact name, pager, protocol
Alternate CRC: Includes contact name, pager, protocol
Primary CRC: Includes contact name, pager, protocol IF APPLICABLE
Alternate CRC: Includes contact name, pager, protocol IF APPLICABLE
Research group: Ex: BOC, TOP
Procedure description: Ex: liver biopsy

Tissue priority:

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</table>
Appendix B: Locations
Appendix C: How are we different from CCPM collaborative projects?

<table>
<thead>
<tr>
<th>DCBC Includes:</th>
<th>DCBC does not include the following services:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sample collection in CSIR</td>
<td>• Collection of biopsies outside of CSIR</td>
</tr>
<tr>
<td>• Allocation of tissue according to tissue priority list provided by study team</td>
<td>• Project management support</td>
</tr>
<tr>
<td>• Hand-off of all tissue to study CRC</td>
<td>• Protocol development support</td>
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<tr>
<td></td>
<td>• MTA/DUA creation</td>
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<td></td>
<td>• Sample tracking</td>
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<td>• Sample storage</td>
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<td>• Chargeback OncoPanel</td>
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<td>• Archival/OSH tissue requests</td>
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<td>• WES/RNAseq</td>
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<td>• Blood biopsies</td>
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<td>• Single cell/nucleus sequencing</td>
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<tr>
<td></td>
<td>• Spatial analysis</td>
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<tr>
<td></td>
<td>• Data analysis</td>
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